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| 08/062,021      | 05/14/1993  | LYNN BERGMEYER       | 67270JLT            | 8501             |

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EXAMINER

JONES, WILLIAM G

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1634

DATE MAILED: 10/04/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/062,021

Applicant(s)

BERGMEYER ET AL.

Examiner

Gary Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on board decision 2/21/2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-13, 16-20, 22-27, 30, 31, 33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13, 16-20, 22-27, 30, 31, 33, 35-37 and 39-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This application has been returned from the Board of Appeals. All previous rejections were reversed by the board and thus are withdrawn.
2. The prosecution is reopened in this application in order to set forth double patenting rejections in view of patents that issued during the prosecution of this application.
3. An attempt was made to contact the attorney of record by telephone to resolve this issue, but that attempt was not successful.

### *Double Patenting*

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 16, 17, 18, 19, 20, 39, 40 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5702901. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*,

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140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Most of the limitations of the rejected claims are recited within the claims of the '901 patent. Limitations that are not specifically recited in the claims are addressed

(a) Instant claim 1 is drawn to a composition which comprises primers specific for hCMV DNA in particular, and claim 1 of the '901 patent is drawn to primers specific for only "target DNA" (see section (a) of both claims). However, claim 6 of the '901 patent specifically discloses hCMV DNA as one of the species that the first and second primers are hybridizable to.

(b) Instant claim 1 recites "each of said first, second, third, and fourth primers being present in the same amount within the range of from about 0.1 to 2  $\mu$ molar." Dependent claim 3 of the '901 patent recites that the primers is present at a concentration of at least about 0.075  $\mu$ molar which is within the range recited in instant claim 1 when 0.075 is rounded to 0.1. Furthermore, the portion of specification of the '901 patent that supports the recitation of the primer concentration teaches that primer concentrations are preferably within the range of from about 0.1 to 2  $\mu$ molar (Col. 12, lines 40-41). Thus, this limitation of instant claim 1 cannot be considered patentably distinct over claim 3 of the '901 patent when there is a specifically recited embodiment of the '901 patent that would anticipate claim 1. Alternatively, this limitation of instant claim 1 cannot be considered patentably distinct over claim 3 of '901 when there is a specifically disclosed embodiment in '901 that supports claim 3 of that patent and falls within the scope of claim 1 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 3 by selecting a specifically disclosed embodiment that

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supports that claim, i.e., the primer concentrations in the range of 0.1 to 2  $\mu$ molar disclosed in '901. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 3.

(c) Claim 1 herein recites a thermostable polymerase present at at least 10 units/100  $\mu$ l. Dependent claim 3 of the '901 patent recites a thermostable polymerase present at from about 0.1 to about 50 units/100  $\mu$ l. Furthermore, the portion of specification of the '901 patent that supports the recitation of the thermostable DNA polymerase concentration teaches that polymerase concentrations are preferably at least 10 units/100  $\mu$ l (Col. 12, lines 39-40). Thus, this limitation of instant claim 1 cannot be considered patentably distinct over claim 3 of '901 when there is a specifically disclosed embodiment in '901 that supports claim 3 of that patent and falls within the scope of claim 1 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 3 by selecting a specifically disclosed embodiment that supports that claim, i.e., the polymerase concentrations of at least 10 units/100  $\mu$ l disclosed in '901. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 3.

(d) Claim 5 herein recites that the first and second primers of claim 1 have the same length in the range from 20-30 nucleotides. This limitation is not particularly recited in the claims of the '901 patent, but is contained within their scope. The portion of the specification of the '901 patent that supports the recitation of the primers teaches that they are preferably the same length in the range from 20-30 nucleotides (Col. 6, lines 11-12). Thus, this limitation of instant claim 5 cannot be considered patentably distinct over the claims of '901 when there is a specifically disclosed embodiment in '901 that supports the claims of that patent and falls within

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the scope of claim 5 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., primers of the same length in the range from 20-30 nucleotides disclosed in '901. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within at least claim 1.

(e) Claims 39 and 40 herein recite particular primers and capture probes that are not specifically recited in the claims of the '901 patent. The portion of the specification of the '901 patent that supports the recitation of the primers and probes teaches these probes as being specific embodiments useful within the instant invention (Col. 8, primer sets 10 and 11 and Col. 10, SEQ ID NO: 8, 49, 50, and 12). Thus, these limitations of instant claims 39 and 40 cannot be considered patentably distinct over the claims of '901 when there is a specifically disclosed embodiment in '901 that supports the claims of that patent and falls within the scope of claims 39 and 40 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., compositions that contain the recited primers and probes. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within at least claim 1.

The limitations of the remaining rejected claims are found within the claims of the '901 patent. Claims 19, 20 and 41 recite that the separate sets of primers are stored separately in the composition. This limitation is obvious in view of the disclosure of the '751 patent because the ordinary practitioner would have been motivated to separately store primers to different target organisms to facilitate ease of use when combining reagents in a multiplex reaction. With regard

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to the kit claims of the instant application, these are obvious over the '901 patent for the same reasons as addressed for the composition claims.

6. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5811295. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the '295 patent contains all of the limitations of instant claim 37 except that instant claim 37 requires "at least one of said capture probes being specific for and hybridizable with hCMV DNA." The portion of the specification of the '295 patent that supports Claim 1 of that patent teaches capture probes drawn to hCMV DNA (Example 5). Thus, this limitation of instant claim 37 cannot be considered patentably distinct over the claims of '295 when there is a specifically disclosed embodiment in '295 that supports the claims of that patent and falls within the scope of claim 37 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., probes to hCMV DNA in '295. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within at least claim 1.

7. Claims 22, 23, 24, 25, 26, 27, 30, 31, 33, 35, 36, and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6174668. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Most of the limitations of the rejected claims are recited within the claims of the '901 patent. Limitations that are not specifically recited in the claims are addressed

(a) Instant claim 22 is drawn to a method for the amplification and detection of hCMV DNA in particular, and claim 1 of the '668 patent is drawn generally to methods for the amplification and detection of target DNA (see at least preamble of both claims). However, claim 12 of the '668 patent specifically discloses hCMV DNA as one of the species that the first and second primers are hybridizable to.

(b) Instant claim 22 recites "each of said first, second, third, and fourth primers being present in the same amount within the range of from about 0.1 to 2  $\mu$ molar." Dependent claim 13 of the '668 patent recites that the primers is present at a concentration of at least about 0.075  $\mu$ molar which is within the range recited in instant claim 1 when 0.075 is rounded to 0.1. Furthermore, the portion of specification of the '668 patent that supports the recitation of the



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primer concentration teaches that primer concentrations are preferably within the range of from about 0.1 to 2  $\mu$ molar (Col. 12, lines 40-41). Thus, this limitation of instant claim 22 cannot be considered patentably distinct over claim 13 of the '668 patent when there is a specifically recited embodiment of the '668 patent that would anticipate claim 22. Alternatively, this limitation of instant claim 22 cannot be considered patentably distinct over claim 1 of '668 when there is a specifically disclosed embodiment in '668 that supports claim 1 of that patent and falls within the scope of claim 22 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 22 by selecting a specifically disclosed embodiment that supports that claim, i.e., the primer concentrations in the range of 0.1 to 2  $\mu$ molar disclosed in '668. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 3.

(c) Claim 22 herein recites a thermostable polymerase present at at least 10 units/100  $\mu$ l. Dependent claim 13 of the '668 patent recites a thermostable polymerase present at from about 0.1 to about 50 units/100  $\mu$ l. Furthermore, the portion of specification of the '668 patent that supports the recitation of the thermostable DNA polymerase concentration teaches that polymerase concentrations are preferably at least 10 units/100  $\mu$ l (Col. 12, lines 39-40). Thus, this limitation of instant claim 22 cannot be considered patentably distinct over the claims of '668 when there is a specifically disclosed embodiment in '668 that supports claim 1 of that patent and falls within the scope of claim 22 herein because it would have been obvious to one having ordinary skill in the art to modify the method of at least claims 1 and 13 by selecting a specifically disclosed embodiment that supports that claim, i.e., the polymerase concentrations of at least 10 units/100  $\mu$ l disclosed in '668. One having ordinary skill in the art would have been

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motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1 and 13.

(d) Claim 22 herein recites that the priming and extension are carried out at the same temperature within the range of from about 62 to about 75° C and carried out within 120 seconds. Claim 7 of the '668 patent recites that priming and extension are carried out at the same temperature within the range of from 62 to 75° C. The claims of the '668 patent do not specifically recite that the priming and extension are carried out within 120 seconds. The portion of the specification of the '668 patent that supports the recitation the length of the priming and extension steps teaches that they are preferably from about 1 to 120 seconds (Col. 14, lines 40-45). Thus, this limitation of instant claim 22 cannot be considered patentably distinct over the claims of '668 when there is a specifically disclosed embodiment in '668 that supports the claims of that patent and falls within the scope of claim 22 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., to carry out the priming and extension step within 120 seconds. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within at least claim 22.

(e) Claims 22 herein recite a capturing step that is recited in claim 8 of the '668 patent.

(f) Claim 42 herein recites methods which utilize specific capture probes and primers that are not recited in the claims of the '668 patent. However, the portion of the specification of the '668 patent that supports the recitation of the primers and probes teaches these probes as being specific embodiments useful within the instant invention (Col. 8, primer sets 10 and 11 and Col. 10, SEQ ID NO: 8, 49, 50, and 12). Thus, these limitations of instant claim 42 cannot be

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considered patentably distinct over the claims of '668 when there is a specifically disclosed embodiment in '668 that supports the claims of that patent and falls within the scope of claims 42 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., compositions that contain the recited primers and probes. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within at least claim 22.

The limitations of the remaining rejected claims are found within the claims of the '668 patent.

8. Claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 16, 17, 18, 19, 20, 39, 40 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5733751. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. The '571 patent sets forth methods for preparing a reaction mixture. The '571 patent does not specifically set forth compositions comprising the reaction mixture or kits comprising the reaction mixture, but in light of the methods of making the reaction mixture, these kits and compositions are prima facie obvious, because the practice of the method of the '571 patent will result in the

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compositions claimed herein. Most of the limitations of the rejected claims are recited within the claims of the '751 patent. Limitations that are not specifically recited in the claims are addressed

(a) Instant claim 1 recites that the composition is buffered at a pH of about 7 to about 9, and the claims in the '751 patent are silent as to the pH of the reaction mixture made by the method. However, the portion of the specification that supports methods for making reaction mixtures demonstrates making reaction mixtures buffered to a pH of 8 (Col. 22, Example 4). Thus, this limitation of instant claim 1 cannot be considered patentably distinct over claim 1 of '751 when there is a specifically disclosed embodiment in '751 that supports claim 1 of that patent and falls within the scope of claim 1 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 1 by selecting a specifically disclosed embodiment that supports that claim, i.e., preparing the reaction mixture at a buffered pH of 8 as disclosed in '751. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(b) Furthermore, instant claim 1 is drawn to a composition which comprises primers specific for hCMV DNA in particular, and claim 1 of the '751 patent is drawn to primers specific for only "target DNA" (see section (a) of both claims). However, the portion of the specification that supports methods for making reaction mixtures demonstrates making reaction mixtures hybridizable to hCMV DNA (Col. 22, Example 4). Thus, this limitation of instant claim 1 cannot be considered patentably distinct over claim 1 of '751 when there is a specifically disclosed embodiment in '751 that supports claim 1 of that patent and falls within the scope of claim 1 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 1 by selecting a specifically disclosed embodiment that supports that

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claim, i.e., preparing the reaction mixture at comprising primers for hCMV DNA. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(c) Instant claim 1 recites "each of said first, second, third, and fourth primers being present in the same amount within the range of from about 0.1 to 2  $\mu$ molar." Claim 1 of the '751 patent is silent with respect to the concentration of primers in the reaction mixture. The portion of specification of the '751 patent that reaction mixtures teaches that primer concentrations are preferably within the range of from about 0.1 to 2  $\mu$ molar (Col. 12, lines 40-41). Thus, this limitation of instant claim 1 cannot be considered patentably distinct over claim 1 of '751 when there is a specifically disclosed embodiment in '751 that supports claim 1 of that patent and falls within the scope of claim 1 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 1 by selecting a specifically disclosed embodiment that supports that claim, i.e., the primer concentrations in the range of 0.1 to 2  $\mu$ molar disclosed in '751. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(d) Claim 1 herein recites a thermostable polymerase present at at least 10 units/100  $\mu$ l. Claim 1 of the '751 patent recites a thermostable polymerase present at from about 0.1 to about 50 units/100  $\mu$ l. Furthermore, the portion of specification of the '751 patent that supports the recitation of the thermostable DNA polymerase concentration teaches that polymerase concentrations are preferably at least 10 units/100  $\mu$ l (Col. 12, lines 39-40). Thus, this limitation of instant claim 1 cannot be considered patentably distinct over claim 3 of '751 when there is a specifically disclosed embodiment in '751 that supports claim 1 of that patent and falls within

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the scope of claim 1 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 1 by selecting a specifically disclosed embodiment that supports that claim, i.e., the polymerase concentrations of at least 10 units/100  $\mu$ l disclosed in '751. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(e) Claim 5 herein recites that the first and second primers of claim 1 have the same length in the range from 20-30 nucleotides. This limitation is not particularly recited in the claim of the '751 patent, but is contained within their scope. The portion of the specification of the '751 patent that supports the recitation of the primers teaches that they are preferably the same length in the range from 20-30 nucleotides (Col. 6, lines 11-12). Thus, this limitation of instant claim 5 cannot be considered patentably distinct over the claim of '751 when there is a specifically disclosed embodiment in '751 that supports the claims of that patent and falls within the scope of claim 5 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., primers of the same length in the range from 20-30 nucleotides disclosed in '751. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(f) Claims 7 and 8 herein recite particular organisms that the primer pairs of the composition are targeted for. These organisms are not particularly recited in the claims of the '751 patent but are specifically disclosed embodiments in the methods of making reaction compositions, as the specification of the '751 patent specifically teaches that pairs of primers to these species are preferred (see at least the examples). Thus, claim 1 of the '751 patent cannot be

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considered patentably distinct from claims 7 and 8 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., primers specific to the particular organisms recited in the examples disclosed in '751. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(g) Claims 11 and 12 herein recite that the primers are labeled with binding moieties, in particular biotin. These organisms are not particularly recited in the claims of the '751 patent but are specifically disclosed embodiments in the methods of making reaction compositions, as the specification of the '751 patent specifically teaches that pairs of primers should be labeled with biotin (Col. 16, lines 26-37). Thus, claim 1 of the '751 patent cannot be considered patentably distinct from claims 11 and 12 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., label the primers with biotin as is disclosed in '751. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

(h) Claims 39 and 40 herein recite particular primers and capture probes that are not specifically recited in the claim of the '751 patent. The portion of the specification of the '751 patent that supports the recitation of the primers and probes teaches these probes as being specific embodiments useful within the instant invention (Col. 8, primer sets 10 and 11 and Col. 10, SEQ ID NO: 8, 49, 50, and 12). Thus, these limitations of instant claims 39 and 40 cannot be considered patentably distinct over the claim of '751 when there is a specifically disclosed

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embodiment in '751 that supports the claims of that patent and falls within the scope of claims 39 and 40 herein because it would have been obvious to one having ordinary skill in the art to modify the method of the claims by selecting a specifically disclosed embodiment that supports that claim, i.e., compositions that contain the recited primers and probes. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

The limitations of the remaining rejected claims are found within the claims of the '751 patent. Claims 19, 20 and 41 recite that the separate sets of primers are stored separately in the composition. This limitation is obvious in view of the disclosure of the '751 patent because the ordinary practitioner would have been motivated to separately store primers to different target organisms to facilitate ease of use when combining reagents in a multiplex reaction. With regard to the kit claims of the instant application, these are obvious over the '751 patent for the same reasons as addressed for the composition claims.

### *Conclusion*

9. Claims 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, 16, 17, 18, 19, 20, 22, 23, 24, 25, 26, 27, 30, 31, 33, 35, 36, 37, 39, 40, 41, and 42 are rejected for double patenting.

10. Claim 38 is allowed. The use of the word "having" in claim 38 has been interpreted herein and throughout the prosecution of this application to mean that the oligonucleotides recited have the sequences as recited with no additional flanking sequences. Thus, these sequences are free of the prior art.




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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jones who can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

October 3, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600